REMARKS

Status of Claims

Prior to this Amendment, claims 1-8 and 10-22 were pending and under consideration. With this Amendment, claims 1-22 have been cancelled, and claims 24-45 are newly added by amendment herein. Thus, after entry of this Amendment, claims 24-45 are pending and under consideration. The amendments of the claims and the various rejections raised in the Office Action are discussed in more detail below.

The Amendments of the Claims

Claims 1-22 have been cancelled in favor of new claims 24-45. Support for the newly added claims is found in original claims 1-22, and throughout the specification.

Specifically, claims 24 and 25 are supported by original claims 1 and 2 and in the specification at paragraphs [0017] and [0018].

Claims 26-29 are supported by original claims 3-6 and in the specification at paragraphs [0018] to [0021].

Claims 30-35 are supported by original claims 7, 8, and 13-15 and in the specification at paragraphs [0022] and [0025].

Claims 36 and 37 are supported by original claims 9 and 10 and in the specification at paragraph [0026].

Claims 38 and 39 are supported by original claims 12 and 16 and in the specification at paragraphs [0023] and [0024].

Claims 40-42 are supported by original claims 1, 18, and 19 and in the specification at paragraphs [0017], [0019], and [0025].

Claims 43-45 are supported by original claims 21 and 22 and in the specification at paragraphs [0028] to [0030].

No new matter is added by virtue of the amendments. Entry into the application is therefore respectfully requested.

Rejection Under 35 U.S.C. § 102(b)

Claims 1-4, 6-8, 20 and 22 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Lorenz, U.S. Patent No. 5,420,197. For the reasons discussed below, the rejection of claims 1-4, 6-8, and 20 is in error, and would be equally in error if applied to the newly added claims. The rejection as applied to claim 22 is discussed separately below.

Before turning to the specific rejections, applicants take this opportunity to answer what may well be the dispositive question posed by the Examiner: "Why must . . . [the claimed] disc or system that comprises a filmogenic polymer and an active agent dissolve on a wetted/wet skin and a prior art system/device that comprises a filmogenic polymer and an active agent not dissolve on a wetted/wet skin?"[1]

The answer is that the claims, by their explicit language, affirmatively exclude filmogenic polymer/agent combinations that are ***un***able to dissolve in water, whereas the cited references, by their own explicit language, affirmatively exclude filmogenic polymer/agent combinations that are able to dissolve in water, defining mutually exclusive sets of compositions. The exclusionary language of applicants' claims is found ***not*** in the claims' recitation of "filmogenic polymer and an active agent", as highlighted by the Examiner, but rather in the additional limitation that the disc "dissolves" upon application to a wetted surface.

To make the distinction more clear, independent claim 24, newly added by amendment herein, recites as follows:

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[1] Office Action, page 3 (emphasis in the original).

24. A delivery device comprising a ***water-dissolvable***, non-tacky, dry uniform layer, wherein the uniform layer comprises a ***water-dissolvable*** filmogenic polymer and an effective dose of an active substance, and wherein the uniform layer is dissolvable upon application onto a wetted skin tissue or mucosal epithelial tissue of a subject.

Turning, then, to the rejections in the Office Action, the Patent Office acknowledges that "Lorenz fails to disclose a delivery disc that dissolves onto a wetted skin and thus does not teach each and every element of the claims."[2] While conceding this distinction, the rejection states that applicants have not demonstrated *compositional differences* between the polymer gels in Lorenz and the claimed device.[3] However, the property of a composition formed from a polymer, or a combination of polymers, to dissolve or remain stable in a particular solvent arises from the chemical and structural characteristics of the polymers that form the composition. Thus, a polymer-based composition that does not dissolve in a particular solvent is chemically and/or structurally different from a polymer-based composition that dissolves in that same solvent. Solubility and stability properties of any composition, including those formed from polymers, is a physical and chemical characteristic. Reiterating the words in the Office Action, "property of a system cannot be separated from the composition/system."[4]

These differences in the properties of compositions formed from various polymers are clearly illustrated in Lorenz, which discloses a polymer-based composition resulting from a combination of certain poly(N-vinyl lactam) and neutralized chitosan. Lorenz emphasizes a number of important points in forming the polymer gels:

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[2] Office Action, page 3.

[3] Office Action, page 4.

[4] Office Action, page 3.

> It is important for the poly(N-vinyl lactam) to contain a degree of ring opened lactam groups. *In the absence of opened lactam rings, the gel does not form.* . . . While the exact nature of the mechanism by which the gel forms is not known, and while it is not intended to be bound by theory, *it is believed to be caused by pervasive and tight hydrogen bonds between chains. The presence of the ring opened pyrrolidones, in some undetermined way, plays an imperative role in achieving this goal.*

(Columns 4-5, emphasis added). The gel resulting from the disclosed combination has a number of desirable and unique properties, such as being "many times capable of absorbing their weight in water" and "*maintaining their physical integrity after absorbing large quantities of water.*" An exemplary embodiment of the polymer gel in Lorenz is given in Example 5 in which the gel preparation displayed the following characteristics:

> It quickly became non-flowable and could be rolled or peeled from the skin. The gel, when put into excess water or saline solution at room temperature, absorbed additional liquid but *did not dissolve or disintegrate.*

The preparation of these gels requires a poly(N-vinyl lactam) having a particular K number (related to molecular weight) and a certain number of acids groups in the polymer. Consequently, not all forms of poly(N-vinyl lactam) will work. This is shown in Example 1 of Lorenz, where a poly(N-vinyl lactam) with a K value of 92 and less than 1 mole equivalent/mole acid groups did not form a polymer gel with chitosan: "*attempts to form a gel using this PVP with chitosan were unsuccessful.*"[5] Thus, the compositions formed by combination of different poly(N-vinyl lactam) and neutralized chitosan are not the same. Likewise, the polymer-based compositions in Lorenz are not the same as the polymer-based uniform layer of the instant claims. Whereas the composition of Lorenz does not dissolve or disintegrate in an aqueous solution, the composition of the uniform layer in the claimed delivery device dissolves upon contact with a moist surface (*e.g.*, wet skin). Hence, the polymer composition of Lorenz is structurally and chemically different from the composition of the uniform layer of the instant claims.

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[5] column 7, lines 24-27.

The descriptions in Lorenz also highlights the level of skill in the art at the time the instant application was filed, which was such that the person skilled in the art had knowledge of which polymers and mixtures of polymers would or would not form compositions with particular characteristics. For example, in addition to the description for the specified combination of poly(N-vinyl lactam) and chitosan to form gels that *do not dissolve or disintegrate* when exposed to aqueous solutions, Lorenz also states that

> Chitosan, a natural product, is derived from chitin. . . . Chitosan becomes *water soluble* when protonated with acids. . . .

As also illustrated by Example 1 of Lorenz, the skilled artisan understood which poly(N-vinyl lactam), chitosan, and combinations thereof would not form compositions with the desired characteristic of being stable in aqueous solutions.

With the above perspective, applicants address the key bases of the rejection, which appears to rest on (1) exclusion from consideration of the "inherent" properties of the uniform layer in the claimed delivery device, and (2) the assertion that because the claims use "comprising" language, it does not exclude the presence of chitosan, which is described in Lorenz. Inasmuch the Patent Office rejection for anticipation rests on the exclusion of "inherent" properties of the composition, this stance is contrary to the examination guidelines and standards for defining the claimed invention for purposes of determining patentability:

> From the standpoint of patent law, a compound and *all of its properties are inseparable*; they are one and the same thing. The graphic formulae, the chemical nomenclature, the systems of classification and study such as the concepts of homology, isomerism, etc., are mere symbols by which compounds can be identified, classified, and compared. But a formula is not a compound and while it may serve in a claim to identify what is being patented, as the metes and bounds of a deed identify a plot of land, the thing that is patented is not the formula but the compound identified by it. And the patentability of the thing does not depend on the similarity of its formula to that of another compound but of the similarity of the former compound to the latter. *There is no basis in law for ignoring any property in making such a comparison. An assumed similarity based on a comparison of formulae must give way to evidence that the assumption is erroneous.*

In re Papesch, 137 USPQ 43, 51 (CCPA 1963); *see* M.P.E.P. §2141.02. Thus, there is no support in the law or the examination guidelines for ignoring any property of the claimed invention when determining patentability. To exclude an element by asserting that it recites an inherent characteristic contradicts the statement in the Office Action that "property of a system cannot be separated from the composition/system." Extrapolation of this same statement to the instant case in fact leads to a conclusion opposite to the Patent Office, namely that the polymer-based composition of Lorenz is not the same as the uniform layer formed by the filmogenic polymers of the claimed subject matter.

This exclusion of composition's chemical properties also contravenes the requirement for consideration of *each and every element of a claim* in determining anticipation. Anticipation under § 102 can be found only when the reference discloses *exactly* what is claimed. . . . " *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780 (Fed. Cir. 1985) (emphasis added).

> **TO ANTICIPATE A CLAIM, THE REFERENCE MUST TEACH EVERY ELEMENT OF THE CLAIM.**
>
> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil. Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). . . . "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

M.P.E.P. § 2131 (8th ed., rev. 2) (heading capitalization and font emphasis in the original). As such, the polymer-based composition (*i.e.*, polymer gel) in Lorenz is a combination of certain poly(N-vinyl lactam) and neutralized chitosan that react to form a product that does not "dissolve or disintegrate" when it comes in contact with an aqueous environment. In contrast, the uniform layer of the instant claims is a polymer-based composition that dissolves when applied to a wet

surface. Thus, the ***composition*** of the instant claims is not the same as the ***composition*** disclosed in Lorenz. The Patent Office's justification for the rejection on the position that the generic claims do not recite a specific polymer or that the specification provides no data is misplaced. Nothing in the anticipation standard recited above states such legal requirements.

Moreover, while the Patent Office attempts to support its reasoning by pointing out that the polymer gel in Lorenz contains chitosan, *a finding of anticipation cannot be based on picking and choosing and combining various disclosed elements within a reference. In re Arkley*, 172 USPQ 524 (CCPA 1972). In essence, the rejection is premised on an understanding that because the polymer based composition disclosed in Lorenz uses at least one of the filmogenic polymers of the instant application, the polymer based compositions of the instant claims are not different from the polymer based compositions disclosed in Lorenz. However, it is not the single polymers used in Lorenz that forms the composition, but a combination of two polymers that react to form a gel having properties different than the individual polymers. The presence of chitosan in the polymer gel of Lorenz cannot be divorced from its use in combination with certain poly(N-vinyl lactams) because the composition that results is stable and does not dissolve when applied to a wet surface, properties that are different from the individual polymers. For example, chitosan used without the specified poly(N-vinyl lactam) produces a composition with entirely different characteristics, namely dissolution in an aqueous environment.

In view of the above, applicants submit that the rejection over Lorenz is in error. The composition of Lorenz is not the same as the composition of a uniform layer that dissolves when applied to a moist surface. Lorenz does not teach each and every element of the claimed subject matter, and therefore does not anticipate the claimed delivery device or methods of its use. Withdrawal of the rejection is respectfully requested.

Claim 22 has been rejected together with claims 1-4, 6-8, and 20 as being anticipated by Lorenz. However, claim 22 is directed to a method of cleansing tissue using a delivery device with a uniform layer comprising a filmogenic polymer and a surfactant. The bases for the rejection of claim 1-4, 6-8, and 20 do not apply to claim 22 because the Patent Office has not

pointed to any part of the disclosure in Lorenz that describes the use of any delivery device with the recited characteristics for cleansing skin. The rejection of claim 22 is in error, and its withdrawal is requested.

Claims 1, 3, and 21 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Leonard et al., U.S. Patent No. 4,820,525. The Patent Office recites the same bases as asserted for the rejection over Lorenz for the rejection over Leonard. Just as the rejection over Lorenz is in error, the rejection over Leonard is also in error and would be equally in error for the newly added claims.

Leonard discloses high molecular weight/high density polyethylene *foam* used as a reservoir for the delivery of drugs. The polyethylene foam is available in sheets or rolled stock, and are described as being commercially available under various trade names, such as "Porex x-4900" and "Porox P-20."[6] The polyethylene foam is impregnated with "liquid" or "semisolid" drug dosage forms. Polyethylene as well as products derived from polyethylene are stable to many solvents. Applicants submit for review Exhibit A, Chemical Fact Sheet for Polyethylene (published by Orica) and Exhibit B, Porex Polyethylene (PE). The polyethylene chemical fact sheet states that "polyethylene is one of the most stable and inert polymers, exhibiting high resistance to chemical attack including alkalis, aqueous solutions, non-oxidizing agents and to a lesser extent oxidizing acids." Under the section entitled "Physical properties," the solubility of PE in water is described as "NIL." The description in the Porex literature provides the following with respect to polyethylene"

> [T]hermoplastic with very good chemical resistance. . . . Products made from standard polyethylene grades typically have pore size diameters ranging from 7 to 150 um. . . . Polyethylene is resistant to concentrated acids, alkalies and many organic solvents.

As discussed above, the filmogenic polymer of the instant claims forms a composition that dissolves when applied to a moist or wet surface. In contrast, the polyethylene polymer used

[6] Column 2, lines 18-29.

in Leonard is known for its chemical stability and inertness: the solubility of the polymer in aqueous solution is **NIL**. The polymer-based composition formed from polyethylene is the antithesis of the composition formed of filmogenic polymers described in the present application. Thus, it cannot be disputed that the claimed delivery device is different from the device disclosed in Leonard, and therefore not anticipated by Leonard.

The Patent Office position for the rejection over Leonard is the same as that asserted over Lorenz, and is therefore improper for the same reasons articulated above. The exclusion from consideration the dissolution characteristics of the polymer-based uniform layer, as well as the reliance of the rejection on picking and choosing isolated elements without considering the invention as a whole, is improper in determining patentability over Leonard. Applicants respectfully submit that arguments set forth for Lorenz apply with equal force to every rejection based on Leonard.

In view of the above, the rejection of the claimed invention is in error, and its withdrawal is respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

Claims 10-19 stand rejected under 35 U.S.C. §103(a) as being allegedly obvious over Lorenz, U.S. Patent No. 5,420,197. The rejection as applied to claims 10-19 reiterates the reasons articulated above for the anticipation rejection. As such, this rejection is in error and would be in error if applied to the newly added claims.

When rejecting the claims under 35 U.S.C. §103(a), the Examiner bears the burden of establishing a *prima facie* case of obviousness. *In re Bell*, 26 USPQ2d 1529 (Fed. Cir. 1993). M.P.E.P. §2142. To establish a *prima facie* case of obviousness, three basic criteria must be met: (1) the prior art must provide one of ordinary skill with a suggestion or motivation to modify or combine the teaching of the references relied upon by the examiner to arrive at the claimed invention; (2) the prior art must provide one of ordinary skill with a reasonable expectation of success; and (3) the prior art, either alone or in combination, must teach or suggest each and

every limitation of the rejected claims. The teaching or suggestion to make the claimed invention, as well as the reasonable expectation of success, must come from the prior art, not applicants' disclosure. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991); M.P.E.P. §706.02(j). If any one of these criteria is not met, *prima facie* obviousness is not established.

The rationale advanced in the Office Action is the same as the one stated in the anticipation rejection over Lorenz. If the Patent Office position is that Lorenz teaches or suggests each and every element of the claimed invention, the stated basis has implicated only one of the criteria required to establish a case of *prima facie* obviousness. The Patent Office has the burden of showing all three requirements enunciated above, and in this case, the Office Action has not set forth a credible basis for why all three criteria are satisfied.

Moreover, although Lorenz discloses polymers such a chitosan and polyvinyl pyrrolidone, the mere recitation of individual elements in a reference is insufficient to establish a *prima facie* case of obviousness unless there is some motivation or suggestion in the reference to combine or modify the elements. In assessing the motivation or suggestion in the prior art, the reference used must be considered in its entirety, *i.e.*, as a whole, *including portions that would lead away from the claimed invention.* M.P.E.P. §2141.02 (emphasis added).

In the instant case, the composition used in Lorenz for the delivery of a therapeutic compound is a polymer-based composition generated from a combination of poly(N-vinyl lactam) and neutralized chitosan. These compositions are stable and do not dissolve or disintegrate in an aqueous solvent. Lorenz clearly discourages the use of chitosan because it is soluble in water. Moreover, as noted above, Lorenz in Example 1 states that the combination of a certain poly(N-vinyl lactam) and neutralized chitosan was not successful in producing the polymeric gel. The direction of inquiry in Lorenz is contrary to the claimed delivery device, and therefore teaches the skilled artisan away from the subject matter of the instant claims. There is nothing in Lorenz for motivating or suggesting to the skilled artisan to modify its teaching to arrive at the claimed device.

Given the teachings in Lorenz, there could hardly be any reasonable expectation of success. The final product in Lorenz is a polymer-based composition that does not dissolve in an aqueous environment. The disclosure in Lorenz does not elude to the use of polymers formed into a composition that dissolves when applied to a wet surface for the transdermal delivery of a therapeutic agent. A skilled artisan attempting to follow the teachings of Lorenz will choose polymers and polymer combinations that form compositions stable in aqueous environments, thereby defeating any reasonable expectation of success in arriving at the claimed subject matter.

Even an assertion that Lorenz teaches or suggests each and every element of the claims is not supported by the facts. The mere mention of polymers chitosan, polyvinyl pyrrolidone, and a transdermal drug delivery device does not amount to a teaching or suggestion for the claimed subject matter because the device described by Lorenz is limited to use of a composition resulting from *reacting* chitosan and poly(N-vinyl lactam), which has characteristics contrary to the claimed delivery device. Nothing in Lorenz teaches or suggests a delivery device with a uniform layer made of chitosan ***or*** polyvinyl pyrrolidone, or a polymer combination in which the uniform layer dissolves when applied onto a moist or wetted surface. When the claimed subject matter is considered as a whole, as required under the examination guidelines, Lorenz fails to teach or suggest each and every element of the claims. M.P.E.P. §2141.02.

For the reasons articulated above, the Patent Office has not met the burden of establishing even one of the criteria required to show a *prima facie* case of obviousness. The rejection is in error and its withdrawal is respectfully requested.

Obviousness-Type Double Patenting

Claims 1, 3, 6, 8, and 15 stand rejected under the judicially created obviousness type double patenting as being obvious over claims 42, 43, and 45-47 of U.S. Patent Application No. 09/340,338.

Applicants acknowledge the position of the Patent Office in reiterating the rejection under M.P.E.P. §804 following applicants' request that the rejection be held in abeyance. As

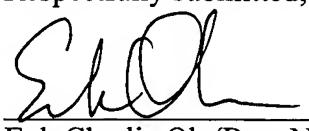
noted in the prior response, applicants will address the obviousness type double patenting rejection once there is allowable subject matter in the application.

Conclusion

Claims 24-45 are believed to satisfy all of the statutory requirements for patentability and are in condition for allowance. An early notification of the same is kindly solicited. If the Patent Office believes that there are further unresolved issues, applicants encourage the Patent Office to contact the undersigned attorney with any questions or concerns by telephone at 415.262.4504.

No fees beyond those included with this response are believed to be due in connection with this Amendment. However, the Commissioner is authorized to charge any additional fees that may required, or credit any overpayment, to Dechert LLP Deposit Account No. 50-2778 **(Order No. 366325-509US)**.

Respectfully submitted,



Date: November 21, 2005

Euk Charlie Oh (Reg. No. 54,345)
Under 37 C.F.R. § 1.34

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POLYETHYLENE

Other names

Polythene
Polyethene
Polyethylene

Molecular formula

$(C_2 - H_4)_n$

Ethylene gas can be polymerised to produce polymers of any desired molecular weight, from oils, greases, and soft waxes at low molecular weights to tough flexible polymers (polyethylene) at high molecular weights.

Physical properties

Density:	900-965 kg/m^3
Bulk Density:	Approx. 500 kg/m^3 (in pellet form)
Autoignition Temperature:	90-130°C
Decomposition Point:	>250°C
Solubility in Water:	NIL

In its basic form, polyethylene is an odourless, translucent solid, usually sold in pellet form for conversion into derivative products. Additives such as stabilisation, slip and antiblock may be present to achieve specific properties. Pigments may be added to obtain coloured products or carbon black for UV protection. The pellets may be converted into powder form.

Polyethylene is one of the most stable and inert polymers, exhibiting very high resistance to chemical attack including alkalis, aqueous solutions, non-oxidising acids and to a lesser extent, concentrated oxidising acids. There may be some affects by organic solvents - at room temperature, polythene resins are almost insoluble in all organic solvents although some absorption, softening or embrittlement may occur. At temperatures above 70°C polythenes will dissolve in some solvents particularly hydrocarbon solvents such as xylene and toluene. The degree of any attack is influenced by the molecular weight of the polyethylene (low molecular weight polymers are more readily attacked than high molecular weight).

Some chemicals such as detergents and silicone oil will cause the phenomena known as environmental stress cracking. Again, molecular weight of the polymer has an influence. Polyethylene is very resistant to water and water vapour and has one of the lowest water absorptions of all commercial plastics.

All oils attack polyethylene to some extent. Mineral oils will dissolve the polymer at elevated temperatures and at lower temperatures they are absorbed causing swelling, discolouration and in the extreme, disintegration. Vegetable and animal oils do not have such a pronounced effect but some may cause environmental stress cracking to occur (tallow for example).

End uses

Polyethylene is a very versatile polymer and is used in a wide variety of applications. The most common is in flexible packaging particularly foodstuffs. This application requires the combination of easy processing into a flexible film, excellent toughness, chemical inertness and the ability to form strong heat seals quickly. Typical flexible packaging examples for low density polythene include bread, frozen food the sealant layer in a laminated structure for confectionery and pet food packaging, the internal/external coating of fibreboard for packaging milk and fruit juices, shrink wrapping and the stretch/cling collation

Exhibit B

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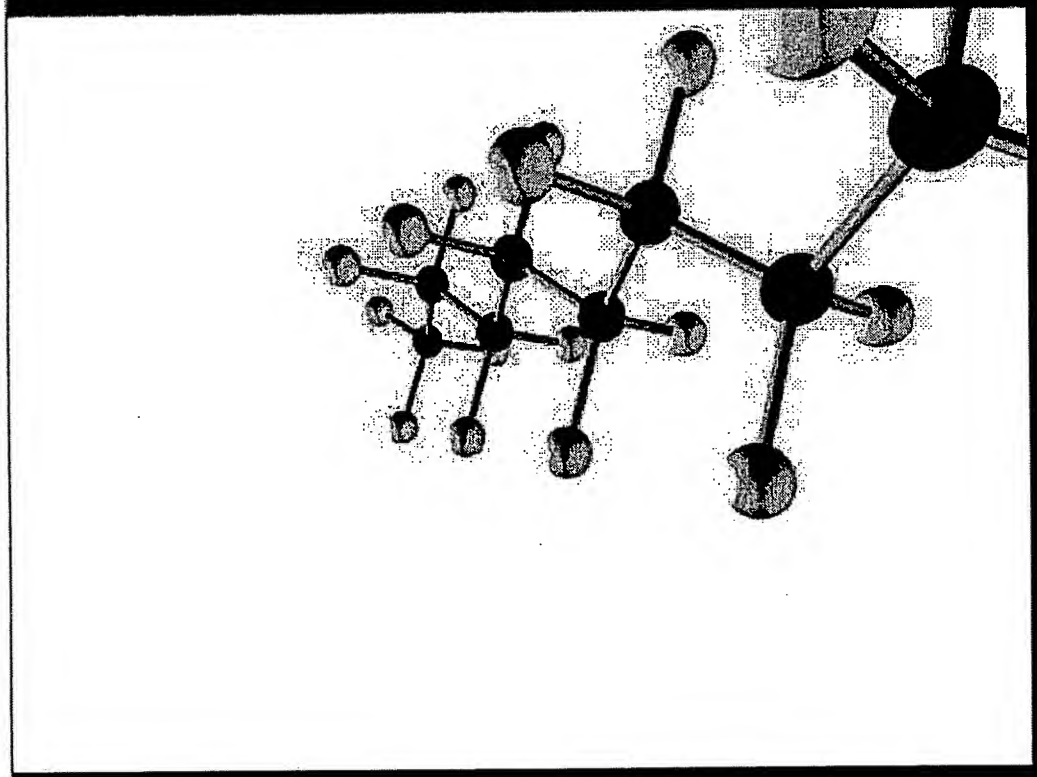

is the most commonly used plastic in the world with annual consumption rates exceeding 50 billion pounds per year. PE is also Porex's most frequently used raw material in the production of Porex's porous plastics. Over 70 percent of Porex's products use polyethylene.

With a linear molecular structure of repeating -CH2-CH2-units, PE is a semi-crystalline polymer. In general, PE is considered a strong, lightweight, thermoplastic with very good chemical resistance. Further, the polymer elongates before breaking, which enhances the toughness of porous parts made from PE. Products made from standard polyethylene grades typically have pore size diameters ranging from 7 to 150 micrometers. However, these nominal values can be increased to 300 micrometers with special blends.

Polyethylene is resistant to concentrated acids, alkalies and many organic solvents. Most of Porex's polyethylene grades are suitable for use in continuous service at temperatures up to 180° F (82°C) and intermittently at 240°F (116°C). If not stressed, Porex's PE grades are stable at 212°F(100°C) in continuous service

PE1
PE2
PE3
PE4
PE5
PE6
PE7

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